

# Navajo Nation Human Research Review Board

## Meeting Agenda

Meeting Date: 2022-03-15 Meeting Time: 9:00 AM  
Location: TeleConference

Teleconference Dial-in: 978-990-5350,  
Access Code: 5891214

### MEMBERS:

Mrs. Beverly Becenti-Pigman - Community	<input type="checkbox"/>
Dr. David Begay, Ph.D. - Scientific Education	<input type="checkbox"/>
Mr. Delvin Yazzie, MPH - Epidemiology	<input type="checkbox"/>
Dr. Kalvin White, Ph.D. - Scientific Education	<input type="checkbox"/>
Dr. Nanibaa' Garrison, Ph.D. - Genetics, Bio-Ethics	<input type="checkbox"/>
Dr. Rebecca Izzo-Manymules, Ph.D. - Chairperson - Education	<input type="checkbox"/>
Dr. Sonya Shin, MD - Medicine	<input type="checkbox"/>
Ms. Ursula Knoki-Wilson, MSN, MPH - Nursing	<input type="checkbox"/>

### OLD BUSINESS:

I. Meeting Call to Order:

II. Roll Call:

- Invocation:

- Introduction:

III. Review and Approval of Agenda:

IV. Review and Approval of September 21, Meeting Minutes:

### NEW BUSINESS:

V. Review and Approval of Quarterly Reports:

VI. New Presentations:

VII. Returing Presentations:

VIII. Serious Adverse Events:

IX. Noon Hours Discussion:

X. Acceptance and Approval of Manuscripts:

XI. Announcements / Adjournment:

## QUARTERLY REPORTS

1. NNR-16.244      PI: Mark Bauer  
Identifying and Reinforcing Positive Behaviors among Dine' College Students  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Reports covering: 1) April 19, 2021 - July 19, 2021, 2) July 19, 2021 -October 19, 2021, 3) October 19, 2021 - January 19, 2022 periods

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2. NNR-17.277      PI: Denise Charron-Prochownik  
Stopping Gestational Diabetes in Daughters and Mothers - Phase 2  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering January 1, 2022 - March 31, 2022 period

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3. NNR-18.311b      PI: Nancy Whitesell  
Multisite Implementation Evaluation of Tribal Home Visiting (MUSE)  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Reports covering: 1- May 20, 2021 - February 19, 2022, 2-August 20, 2021 - November 19, 2021, 3-November 20, 2021 - February 19, 2022 periods

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4. NNR-19.363      PI: Charlene Poola  
Tribal Equine Assisted Psychotherapy: Building Youth Resiliency through Horses  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering 1) August 1, 2021 - October 30, 2021, 2) November 1, 2021 - January 31, 2022 periods

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5. NNR-20.373T      PI: Vincent Werito  
Cultural Characteristics of Successful Aging from a Dine Perspective: The Significance of Dine Elder knowledge in Achieving Long-Life Happiness as community well-being  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Reports covering: 1) September 12, 2021 - November 12, 2021, 2) November 12, 2021 - February 12, 2022 periods

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6. NNR-20.380      PI: Regina Eddie  
Examining School Wellness in American Indian Communities  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering December 1, 2021 - February 28, 2022 period

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7. NNR-20.381      PI: Laura Hammitt  
A Phase 1/2/3 Placebo-Controlled, Randomized, Observer-Blind, Dose-Find Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of SARs-COV 2 RNA Vaccine Candidates Against COVID-19 in Healthy Adults (Short Title: Pfizer COVID-19 Vaccine Study)  
Reason on Agenda: (Other)  
Description: Request Acceptance and Approval of Medwatch Safety Report #2021699328 Follow up February 4, 2022 #7

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8. NNR-21.395T      PI: Michelle Tsosie  
The Transformative Influence of Stories in the Lives of Navajo Women: A Narrative Inquiry  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering October 20, 2021 - January 19, 2022 period

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9. NNR-21.423 PI: Akash Gupta  
Evaluating the Impact of the Gallup COVID-19 Respiratory Shelter  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering November 8, 2021 - January 31, 2022 period
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10. NNR-21.427 PI: Lorenda Belone  
Family Listening Program a Culturally-Centered Dissemination & Implementation Project  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering November 16, 2021 - February 28, 2022 period
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11. NNR-21.428 PI: Vincent Werito  
Wide Engagement for Assessing Vaccine Equity in New Mexico (WEAVE NM)  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering November 16, 2021 - February 16, 2022 period
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12. NNR-11.349 PI: Mark Bauer  
Navajo Gardening, Nutriiton, and Community Wellness  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Reports covering: 1) April 17, 2021 - July 17, 2021, 2) July 17, 2021 - October 17, 2021.  
3) October 17, 2021 - January 17, 2022 periods.
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13. NNR-19.358T PI: Sonya Shin  
Inter-generational Impact of Navajo Fruit and Vegetable Prescription (FVRx) Program  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering September 17, 2021 - December 17, 2021 period
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#### NEW PRESENTATION(S)

1. NNR-22.439 PI: Ann-Perry Witmer  
Contextualization of Rural Infrastructure Systems for Improved Sustainability  
Reason on Agenda: NEW  
Description: Remarks: Request Review and Approval of New Study; Date Received - 02/28/2022
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2. NNR-22.436 PI: Franklin Sage  
The Changing Landscape and Climate of Dine'tah  
Reason on Agenda: NEW  
Description: Remarks: Request Review and Approval of New Study; Date Received - 01/31/2022
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3. NNR-22.437 PI: Donnie Begay  
The Lifeworld of Navajo Millennials: Seeking Balance and Harmony in their world and others  
Reason on Agenda: NEW  
Description: Remarks: Request Review and Approval of New Study; Date Received - 02/01/2022
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4. NNR-22.438 PI: Samantha Hipolito  
Perceptions of Food Security on the Navajo Nation; A Narrative Analysis of Navajo People's Reflections on Food Security  
Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 02/02/2022

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#### FINAL REPORT

1. NNR-21.418 PI: Keona Manuelito

Socio-environmental and psychosocial influences on the diet intentions of Navajo Children

Reason on Agenda: Final Report

Description: Request Acceptance and Approval to Close Study, submission of Transfer Data to Navajo Nation.

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2. NNR-18.299 PI: Wade Campbell

The Ethnoarchaeology of Navajo Pastoralism

Reason on Agenda: (Other)

Description: Request Acceptance and Approval to Close Study, attached Dissertation Committee Signature request by the NN IRB from 1-25-22 Meeting.

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#### RETURNING PRESENTATION(S)

1. NNR-19.332 PI: Gyan Nyaupane

Understanding the changing relationships of Indigenous peoples with their natural environments: A cross-cultural Study

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 19, 2022 - February 19, 2023 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 19, 2020 - February 19, 2021 period.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) November 2020 - January 2021; 2) February 2021 - April 2021; 3) May 2021 - July 2021, 4) August 2021 - October 2021 periods

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2. NNR-19.333 PI: Kevin Lombard

Engaging Navajo Elementary Schools in Randomized Controlled Trial of Y'eego! Healthy Eating & Gardening

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering May 19, 2021 - August 17, 2021 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 17, 2021 - February 15, 2022 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 16, 2022 - February 21, 2023 period

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3. NNR-19.347 PI: Davis Henderson

Navajo Children with and without Speech Sound Disorders

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add Star School of Flagstaff, AZ to participate in Study.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering November 1, 2021 - January 31, 2022 period

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4. NNR-21.398T PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of COVID-19 Mtigation Focus Group Guide

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5. NNR-18.312 PI: Laura Brown

Lactation and Technology for Community Health (LATCH)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering August 21, 2020 - August 17, 2021 period, with copy of Published Manuscript Titled Breastfeeding Attitudes and Practices in a Rural Utah Navajo Community

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6. NNR-04.145 PI: Johnnye Lewis

Dine Network for Environmental Health Project (DINEH)

Reason on Agenda: Annual Report

Description: Request Acceptance and Approva of Annual Report covering July 21, 2020 - July 20, 2021 period

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7. NNR-18.330 PI: Laurie Hudson

Thinking Zinc

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation of Scientific Poster Titled: Thinking Zinc: A nutritional intervention for metal toxicity. at Society of Toxicology in San Diego, CA on March 29, 2022

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 22, 2021 - January 21, 2022 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covereing January 22, 2021 - Janary 21, 2022 period

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8. NNR-18.302 PI: Mark Bauer

Navajo NARCH Partnership: Evaluation of the Student Enhancement Program

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract for CDC Annual OT18-1803 Recipient Meeting on March 23, 2022.

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 17, 2021 - October 17, 2021 and October 17, 2021 - January 17, 2022 periods

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9. NNR-18.296 PI: Mark Bauer

Secondary Data Analysis of American Indian students resilience through digital storytelling and final projects in the Dine College

Summer Research Enhancement Program Curriculum

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering February 20, 2022 - February 20, 2023 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) February 20, 2021 - May 20, 2021, 2) August 20, 2021 - November 20, 2021, 3) November 20, 2021 -February 20, 2022 periods.

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering February 20, 2021 - February 20, 2022 period

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10. NNR-15.201 PI: Mark Bauer

An Intervention to Promote Navajo Gardening, Nutrition, and Community Wellness

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 17, 2022 - March 17, 2023 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Approval of Quarterly Reports covering: 1) March 17, 2021 - June 17, 2021, 2) June 17, 2021 - September 17, 2021, 3) September 17, 2021 - December 17, 2021, 4) December 17, 2021 - March 17, 2022 periods

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 17, 2021 - March 17, 2022 period

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11. NNR-01.081 PI: Mark Bauer

Making a Difference: The Role of Family Support in Navajo Diabetics' Selfcare

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 27, 2022 - March 27, 2023 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) December 27, 2021 - March 27, 2022, 2) March 27, 2021 - June 27, 2021, 3) June 27, 2021 - September 27, 2021, 4) September 27, 2021 - December 27, 2021 periods

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 27, 2021 - March 2, 2022 period

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Reason on Agenda: Final Report - Dissertation

Description: Request Acceptance and Approval of Dissertation Titled: Iina Dzill Be'at'iin (on the path of a strong life); Din'e (Navajo) Perceptions of Self-Care and Social Support with Diabetes Management in submittal in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy Communication for Chenoa Bah Stilwell-Jensen.

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12. NNR-21.431 PI: Allison Barlow

Evaluation of Navajo Safe Water Access Projects

Reason on Agenda: Addendum

Description: Request Acceptance and Approval of Addendum of Proposal Budget page per the NNHRRB request as Conditional Approval

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13. NNR-20.374 PI: Laura Hammitt

Immunogenicity of H, Influenzae type b PRP-OMP vaccines in American Indian and Alaska Native Children (the HibVax Study)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 28, 2022 - April 28, 2023 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering April 28, 2021 - April 28, 2022 period

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14. NNR-21.405T PI: Emily Haroz

Pilot Evaluation of Psychological First Aid for Frontline Workers in American Indian/Alaska Native Communities

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering April 20, 2022 - April 20, 2023 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approva of Annual Report covering April 20, 2021 - April 20, 2022 period

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15. NNR-21.401 PI: Jennifer Richards

Evaluation of Azhee Bidziil (Strong Fathers) Program: Improving Outcomes Among Rural Fathers and their Families.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Protocol to revise questions to the Pre-Outcome Assessment.

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16. NNR-21.414 PI: Laura Hammitt

Phase 3 Master Protocol to Evaluate additional Dose(s) of BNT162B2 in Healthy Individuals previously Vaccinated with BNT162B2

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment 7 to Sub-study E (BNT162b2 bivalent (BNT162b2 Wild Type and BNT162b2 OMI).

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Reason on Agenda: Quarterly Review

Description: Request Acceptance and Approval of Medwatch Safety Report #2021699328 Follow up February 4, 2022 #7

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Data Safety Monitoring events data during months of August 2021 - January 2022

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17. NNR-18.307 PI: Laura Hammitt

Safety and Immunogenicity of V114 in Adults at Risk for Pneumococcal Disease (Adult PCV15 Study)

Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination of Public Summary Document for Vaxneuvance in Australia, includes results from Navajo Nation enrolled participants.

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18. NNR-15.199 PI: Sonya Shin

REACH for Healthy Navajo Communities.

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Edit Customer Intercept Survey

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering December 17, 2021 - March 17, 2022 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approva of Annual Report covering March 17, 2021 - March 17, 2022 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 17, 2022 - March 17, 2023 period

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19. NNR-16.263 PI: Robin Harris

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 1, 2021 - November 29, 2021 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 29, 2020 - November 29, 2021 period

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Reason on Agenda: Consent Modification

Description: Request Acceptance and Approval of Revised Consent Form

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20. NNR-21.409 PI: Carmen George

Expanding and Evaluating a community-based intervention to increase healthy beverage consumption by Navajo Preschool Children

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 21, 2021 - January 20, 2022

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Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of additional methods to collect data, and to offer \$25 gift card.

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21. NNR-20.384 PI: Dornell Pete

Assessing the Gut MicroBiota and Individual Diet in the Navajo ('Abid Study)

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Conference Presentation of Poster Titled: Assessing the Gut MicroBiota and Individual Diet in the Navajo Nation on April 8-13, 2022

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22. NNR-20.391 PI: Heidi Brown

Impact of the COVID-19 Pandemic on Navajo Adults and Health Care Providers

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 1, 2021 - December 31, 2021 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 15, 2022 - March 15, 2023 period

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#### SERIOUS ADVERSE EVENT

1. NNR-19.357 PI: Laura Hammitt

A Phase 3 Randomized, Double, Placebo-controlled Study to evaluate the Safety and Efficacy of MEDI 8897, a Monoclonal Antibody with an Extended Half-Life Against respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: COVID-19

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Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Suspected Unexpected Serious Adverse Reaction: November 4, 2021 (Neonatal Fever), November 24, 2021 (Follow-up), January 28, 2022 (second follow-up), February 18, 2022 (third follow-up)



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2.        NNR-02.110            PI: Vallabh Shah  
Diabetes Prevention Program Outcomes Study (DPPOS)  
Reason on Agenda: Primary - Off Site SAE  
Description:  
Diagnosis: COVID-19

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*Last Page and End of Agenda*